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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,783	01/22/2002	Peter Pal Varga	T9376.DIV2	8745

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EXAMINER

WILLSE, DAVID H

ART UNIT PAPER NUMBER

3738

DATE MAILED: 05/12/2004

121

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/055,783

Applicant(s)

VARGA ET AL.

Examiner

Dave Willse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-69 is/are pending in the application.
- 4a) Of the above claim(s) 41, 68 and 69 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 42, 43 and 65-67 is/are allowed.
- 6) ☒ Claim(s) 32-40, 44-46, 48-52, 54-56, 59 and 62 is/are rejected.
- 7) ☒ Claim(s) 47, 53, 57, 58, 60, 61, 63 and 64 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2 and 7.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Claims 41, 68, and 69 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32-35, 37-40, 48, and 51 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kyocera, JP 9-122160 A. The threaded engagement of the screws imparts compressive forces across portions of the vertebral bodies between the threads and the spinous process plate **B** so as to maintain said engagement. During and after the implant procedure, any

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action tending to draw posterior portions of the adjacent vertebrae **F** apart is resisted by a reactive compressive force exerted by the plate **B**. And since both anteflexion and retroflexion can occur (page 6, lines 4-7, of the English translation), the surgeon having to draw posterior portions of the adjacent vertebrae **F** together in some patients so as to set a desired spacing and alignment of said portions would have been inherent. Regarding claim 34, sagittal alignment is illustrated in Figure 2(b) at plate **B** and is also inherent from the size and shape of the spacer **1** (page 6, paragraph 0016, of said translation). Regarding claim 40, the plate **B** is deemed to comprise rod *members* separated by the openings.

Claims 36, 44-46, 49, 50, 52, 54-56, 59, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kyocera, JP 9-122160 A. The further limitations of claim 36 would have been immediately obvious, if not inherent, from the location of the spacing member **1** as depicted in Figure 2(b). Regarding claim 44, the rod or plate **B** being supplemented or replaced by a *plurality* of rods would have been obvious in order, for example, to stabilize other portions or sides of the spinous processes. The “self-bone” **T** (JPO English abstract; Figure 2(b)) being obtained via the well known step set forth in present claim 45 or 49 would have been immediately obvious to the ordinary practitioner because portions of vertebral bodies are typically removed to allow implant insertion or because providing harvested bone in advance simplifies the surgical procedure. Regarding claims 46 and 50, lamina spreaders were likewise commonly used in the art and would have been obvious in order to facilitate the insertion of the implants **1** and **B**. Regarding claim 52, bringing adjacent vertebral bodies closer together on a posterior side would have been obvious in order to conform to the natural anatomy for certain segments of the spinal column. Regarding claim 55, threading a trocar onto the spacer **1**, a well

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known combination, would have been obvious in order to facilitate insertion of the spacer.

Regarding claim 56, hollow sheath members were also common in the art and would have been obvious in order to prevent tissue trauma (e.g., by the spikes 5) during deployment.

Claims 47, 53, 57, 58, 60, 61, 63, and 64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 42, 43, and 65-67 are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6,648,915: drawings; column 5, lines 29-40;

DE 26 49 042 C2: Figure 12b;

JP 5-208029 A: Figure 2.

The Applicant's remarks have been reviewed and are adequately addressed above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is (703) 308-2903. The examiner can normally be reached Monday through Thursday and often on Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Dave Willse
Primary Examiner
Art Unit 3738